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#116
PATENT-204

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Serial No.: 09/941,237
Filing Date: August 28, 2001
Art Unit: 3732
Examiner: Melba N. Bumgarner
Applicant: Chapoulaud et al.
Title: CUSTOM ORTHODONTIC APPLIANCE FORMING
METHOD AND APPARATUS
Atty Docket: ORM-166CI

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RECEIVED
DEC 23 2003
TECHNOLOGY CENTER R3700

DECLARATION OF CRAIG A. ANDREIKO
UNDER RULE 131 (37 CFR 1.131)

In support of the response of December 15, 2003, to the office action dated August 15, 2003, the Declarant, Craig A. Andreiko states:

1. I am one of the inventors of the subject matter of the present application.
2. I have read the declaration of Joseph R. Jordan dated December 9, 2003. The exhibits attached to it show the following:

Exhibit 1 shows co-inventor Eric Chapoulaud beside a Sanders Model Maker machine made by Sanders Prototype, Inc. set up and operable in our laboratory at Ormco Corporation in Glendora, California, prior to July 10, 1998, the filing date of the provisional patent application that is identified as a related U.S. application on the face of U.S. Patent No. 6,322,728 of Brodtkin et al.

Exhibit 2 shows the machine of Exhibit 1 operating before July 10, 1998 to make, by jet printing layer-by-layer, a wax pattern for investment casting orthodontic brackets.

Exhibit 3 shows the wax pattern of Exhibit 2, as partially completed before July 10, 1998, formed of a green wax having a relatively high melting point surrounded by red wax having a relatively low melting point.

Exhibit 4 shows the wax pattern of Exhibit 3, made before July 10, 1998, after the red wax has been melted away by heat.

Exhibit 5 shows a sprue assembly, prepared before July 10, 1998, that includes the wax pattern of Exhibit 4 for investment casting orthodontic brackets.

Exhibit 6 shows an orthodontic bracket made by investment casting at Ormco prior to July 10, 1998, using the sprue assembly of Exhibit 5.

Exhibits 1-6 relate to the making of orthodontic brackets by and under my direction at Ormco Corporation, the assignee of the present application, by the invention claimed in the present application.

3. Exhibits A and B attached to this declaration are copies of pages dated prior to July 10, 1998, that I made from the laboratory notebook of Eric Chapoulaud that are among the laboratory records in my custody at Ormco Corporation that relate to a project that resulted in the present invention. These pages show and describe the following:

Exhibit A is a notebook page to which are attached two photographs. The upper photograph is an enlarged view of the boundary between red and green wax of a partially completed pattern of which that shown in Exhibit 3 is representative. The lower photograph shows part of a set of orthodontic brackets, of which that shown in Exhibit 6 is representative, made by investment casting from the pattern depicted in the upper photograph. The handwriting on Exhibit A is that of Eric Chapoulaud.

Exhibit B shows a page, subsequent to that of Exhibit A from the same notebook, to which are attached two photographs. The upper photograph is an enlarged view of a portion of a partially completed pattern of which that shown in Exhibit 3 is representative. The lower photograph shows part of a set of orthodontic brackets, of which that shown in Exhibit 6 is representative, made by investment casting from the pattern depicted in the upper photograph. The handwriting on Exhibit A is that of Eric Chapoulaud.

4. Exhibits C and D attached to this declaration are copies of photographs dated prior to July 10, 1998, that are among the laboratory records in my custody at Ormco Corporation that relate to the present invention. These photographs show the following:

Exhibit C shows one of several green wax patterns, made at the direction of and for the inventors hereof, according to the present invention, for making an orthodontic bracket.

Exhibit D shows an orthodontic bracket made according to one of the patterns referred to in the description of Exhibit C.

5. Exhibit E attached to this declaration is a copy of a three page memorandum from among my laboratory records at Ormco Corporation that relate to the present invention. This memorandum is dated prior to July 10, 1998 and was written by Eric Chapoulaud to me and two others at Ormco Corporation. This memorandum is dated and was delivered to me prior to June 20, 1997, which is the filing date U.S. provisional patent application serial no. 60/050,342, which is identified on the face of U.S. Patent No.5,975,893 to Chishti et al.

6. In Exhibit E, Eric Chapoulaud describes our efforts made before June 20, 1997 to evaluate 3D solid freeform manufacturing devices for making custom orthodontic brackets designed by our Elan system, one version of which is that described in U.S. Patent No.5,431,562, and a newer version of which is described in the present application. The devices evaluated included two versions of devices for making custom orthodontic brackets layer-by-layer, including by stereolithography and by wax "3D plotting" for investment casting.

7. In the course of our evaluation referred to in Exhibit E, wax patterns for orthodontic brackets were made for us at our direction by a manufacturer of the wax 3D-plotting devices before June 20, 1997, as shown in Exhibit C, from which we made orthodontic brackets before June 20, 1997, as shown in Exhibit D.

8. Also in the course of our evaluation referred to in Exhibit E, we had in our possession in our laboratory at Ormco Corporation two models of Sanders Model Maker machines. A first model of a Sanders Model Maker machine was installed and operated prior to June 20, 1997, to produce, from files generated by our Elan system, patterns and custom orthodontic brackets according to the process shown in Exhibits 1-6. The slides from which Exhibits 1-6 were made were taken from the operation in our laboratory of one of these Sanders Model Maker machines.

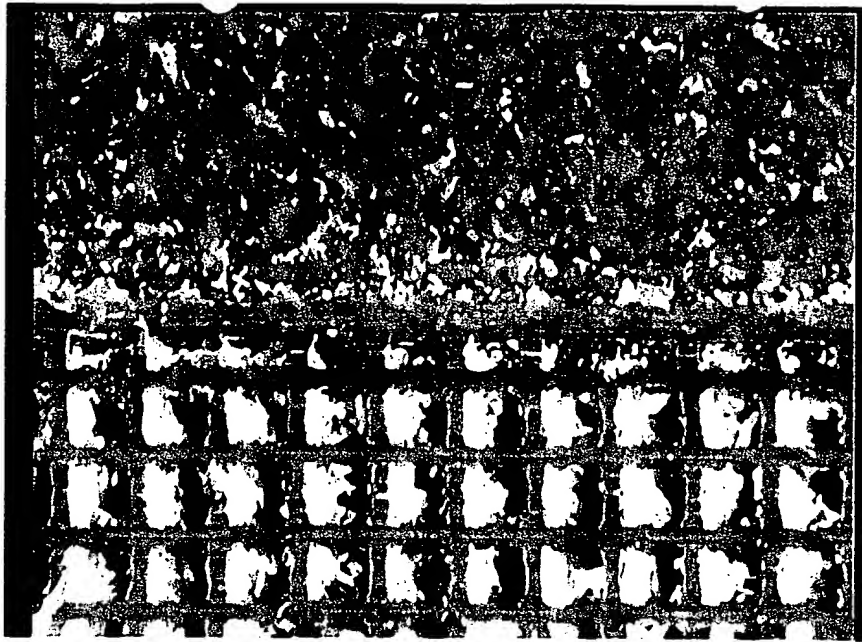
9. Exhibits A and B refer to the tests made with the second model of the Sanders Model Maker machine, the Model Maker II.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

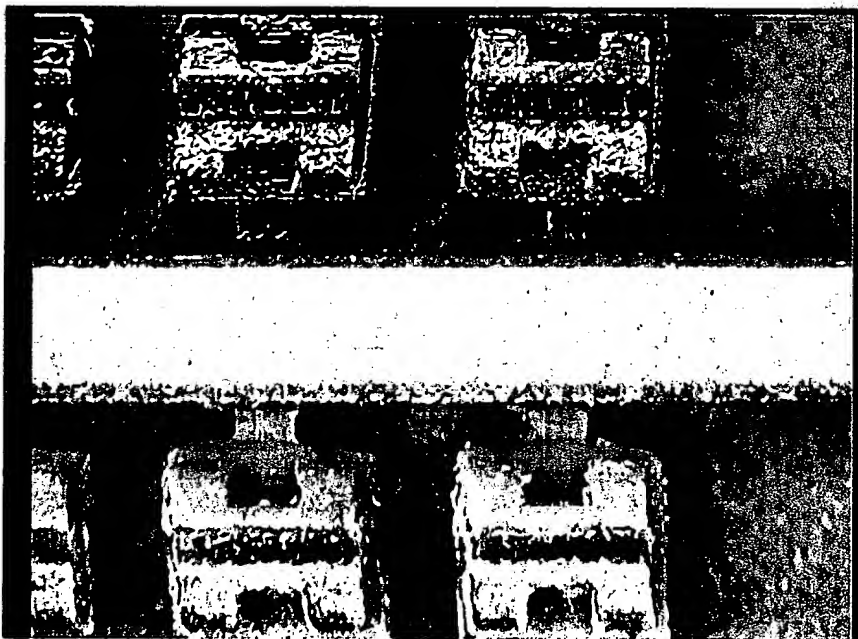


Craig A. Andreiko

12-9-03
Date



Volume: 120 185



BRCKTRES [REDACTED] Finished OK No BERT interception

NEXT PART: Improve the det(?), Raise set voltage to lay down more material

• VOLUME TEST

Build: [60][13] 127.7 127.7 127.6 129.3

Support: [60][11] 92.8 92.7 92.7

EXHIBIT

9

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BACKTREE .mm2 Stopped Completed.

Started: 18:31

① Cutter is clean at the end of the model.

End: 7:52

② Build det Failure

Time:

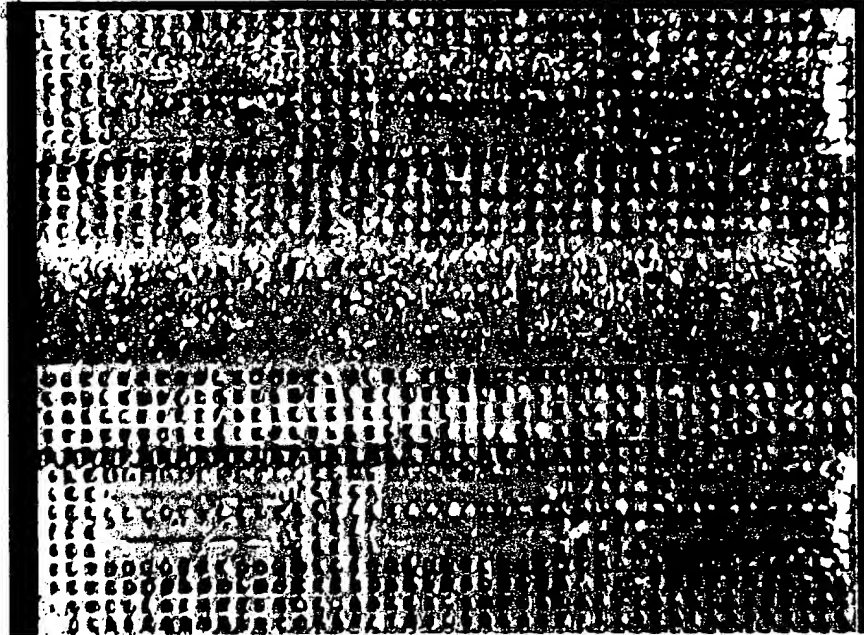
5:21
13:21 MZ

L23 → Hot purge / Purge by user

290 layers

L81 → Hot purge

Model scans OK



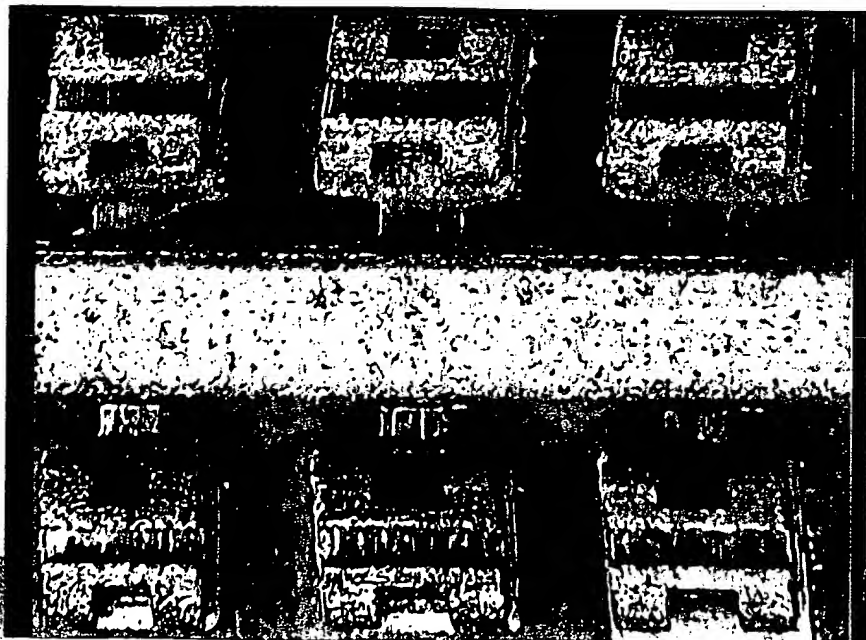
TOP VIEW PART WITH
SUPPORT

BATH: 15°C 60 min ULTRASONIC STARTED 8:16 AM

60 min

Increase T/ 50°C

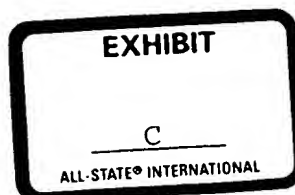
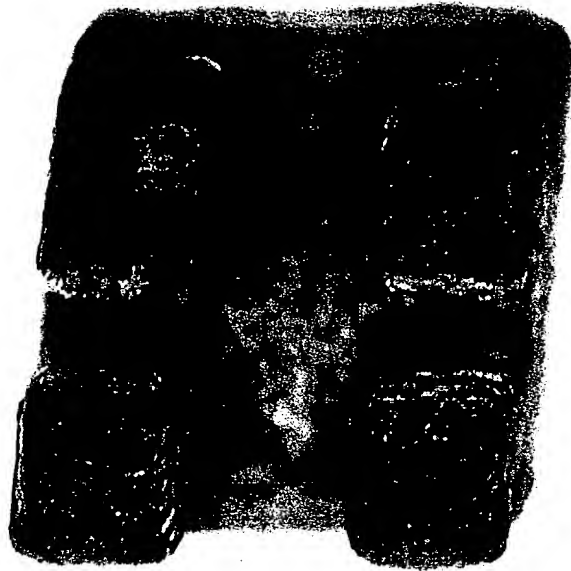
ENDED 12:30 PM



EXHIBIT

8

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EXHIBIT

 D

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Craig: Please RETD

Date: [REDACTED]
From: Eric CHAPOULAUD
To: Albert RUIZ-VELA, Craig ANDREIKO,
Dan EVEN
(c):

SANDERS Prototype:
Wax printing Device
Evaluation Visit

Since a few months, Craig ANDREIKO and myself have been evaluating 3D Solid freeform manufacturing devices that could be connected to our ELAN application and able to manufacture directly customized brackets. The technology currently available offers different type of materials among them photo-polymerisable (Stereo-lithography) and wax (3D plotting), and more important for our application, low resolution and accuracy except for the Model-maker 3D plotting device manufactured by SANDERS prototypes Inc.

Currently, the SANDERS Model Maker machine is the only one that can reach our accuracy needs: < 0.001 inch by offering the possibility of a 0.0005 inch resolution. We have conducted some tests with the west coast distributor by having him manufacturing parts that were created with our CAD software, and further with our new ELAN application software. The results have been promising in respect to the general aspect of the wax parts "plotted" and the dimensions as well. We have good hopes that this machine would allow us to manufacture customized brackets.

Nonetheless, we think that our application is sufficiently outside of the usual utilization of such machine that we have been advised by the local distributor that we should meet with the manufacturer in New Hampshire in order to point out the specifics of our application and discuss with him modifications and optimization possibilities in regard to our process. This meeting took place in WILTON N.H. on [REDACTED] involving E. CHAPOULAUD for ORMCO and Mr MACINTYRE (National Sales V.P.), WIGAND (Technical Development), <<Chris>> (Customer Support) and Mrs COLLINS (Training) for SANDERS Prototype. The Object of the meeting was to discuss our specific needs and the machine characteristics with Application and development engineers, discuss some interface problems and solutions, as well as communication between our software application and the software that drives the machine with software development engineers and discuss the training aspects for our in house operator.

1) SANDERS Prototype Inc.:

This company has been created [REDACTED] on the basis of patents on a wax printing technology, to develop and commercialize a "3D Plotting System" that is named "Model Maker™". It currently employs 50 people and has shipped over 80 Model Maker machines (each machine is listed at \$60 000), which is its only commercialized product.

They are located in WILTON N.H. (small town in the outskirts of NASHUA N.H. about 60 miles north of BOSTON). Its President is Mr Anthony FINIZZIO. The medical supply company BAXTER recently acquired a 20 % stake of SANDERS (Contact at BAXTER is: Paul DIPERNA (847) 270 5502).

2) Model Maker: Desktop 3D Modeling System

Their product presents itself as a desktop unit that supports the CAD designer's workstation environment, allowing designers the ability of creating a physical 3D Model from their CAD design. This machine uses the same technology used in "inkjet printers" adapted to deposit thermo-wax droplets in successive layers allowing the build of 3D Objects from ground up. As we said above, our interest in this technology relies on their ability to use small layers (0.0005 in or 5 tenth of thousands of an inch, 12.5 micrometers) to create the 3D model. This machine is the only machine currently marketed that allows such small layers.

On a software point of view, this machine is usually connected to a PC Computer running a specific application program developed by SANDERS. This program uses ".STL" files as inputs. These type of files

From: Eric CHAPOULAUD

Date: [REDACTED]

SANDERS Prototype / Evaluation Visit

EXHIBIT

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can be created by most of the CAD programs, including SolidWorks, from their own geometry format. The Sanders program can also accept other formats which will be discussed further. The ".STL" file is first "sliced" into a number of layers representing each layer's perimeter of material. Then these layers are used to create the jet-heads travel paths that will construct the 3D model. This machine operates as a inkjet printer that fills the contours representing the layers. Using well known software technology, it moves the jet heads in straight lines between each end of the contours, filling up the inside of the perimeter of layers.

In order to produce accurate layer depths, the machine deposit more wax than necessary, waits for the wax to cool and uses a cutter to cut off the excess material. On the positive side, this process allows the machine to be able to produce layer thicknesses down to 5 tenth, but it also gives a slow process since cooling waiting time becomes a big factor in the model manufacturing time.

Since each layer of Wax need to be deposited on "something" to construct the model, **Model Maker** deposit a layer of another material to be used as support for counter-parts in the model. This material is also Wax, but has a lower melting point temperature, that allows this support material to be removed after the model is built. A cleaning phase is then necessary in order to have the finished Wax part. Please refer to the documents in annex for more information.

This machine has been marketed for almost a year, and customers reaction and comments have lead Sanders into upgrading the **Model Maker** to a new version that will be available in 8 months from now according to their National sales V.P. This machine, called "**Model Maker II**", shows improvement in mainly three aspects: Speed improvement in the Jet Heads Motion and head's wax delivery rate, Reliability and Speed improvement by air conditionning the printing space, Usability improvement by improving the building space to 12 x 6 x 9 inches against 6 x 6 x 6 inches for the current machine. According to Sanders, they are working on improving their material as well. In fact the new machine includes Higher temperature Wax-jets, allowing the possibility of stronger build material along with a better separation with the support material.

The current version of the machine is priced at \$ 59 900, while the new machine will priced at \$ 64 900. Sanders proposes the possibility of ordering the new machine as of now. Sanders will deliver the current version at the current price and when the new version is ready (), it will be installed for an additional \$ 10 000.

3) Characteristics and Specifications

>> See with Rob Connelly (Users Group)

4) Training and Operation

With the purchase of the machine, a training session is offered for 2 or 3 people for a duration of 2 days. It includes training on the software and hands on the machine parameters. Sanders suggested that this training can be extended for another day allowing future users to work on their own parts, getting usefull suggestions and advises directly on their type of models.

The software is relatively easy to use, specially to an operator familiar with 2D/3D CAD design programs. The software works on any platform (Windows 3.1, Windows 95 or Windows NT). The new version that I was demonstrated is simpler than before and provides the operator with fewer options, for a less confusing environment. The current control software works with DOS, but does not involve any experience on DOS.

Everybody at Sanders stressed upon that experience is the key of success in using their machine. Our operator would have to run lots of different parts and orientation in order to be very familiar to the machine behavior and produce good parts with sufficient repeatability and reliability. This machine needs to be taken good care of since it involves a lot of moving parts and "messy" wax drops.

Last month, a first meeting of a new **User's group** was held. This group is set aside Sanders influence while Sanders welcomes the initiative. This group is organized to share information and experience about **Model Maker**. This is most certainly a mine of information our operator could use.

5) Application development Toolkit

Sanders **Model Maker** machine is usually used as a peripheral of a CAD workstation, allowing designers to "print" a 3D model of the part they design. On the other hand, we think that we can use this machine to manufacture small quantities of brackets (ie: new products for clinical tests) and further, use the **Model Maker** machine to manufacture customized brackets along with the Elan program. Using the 3D Modeler, we can design a software that creates completely the brackets, according to the particular dimensions of each tooth, and send these design to the Wax printer to create a master to use to cast the finished part. This is a new and specific application for Sanders.

After discussion with John WIGAND (Technical Development), Sanders was interested in extracting a library of functions from their current program. This library would allow us to use their machine as a new device in our program, keeping our User interface. Our software would be able to launch the printing of the parts and get a status of execution. We also decided that ".STL" files was not a good interface between our softwares. We were supported by Al HASTBACKA in that direction. We would send "slice files" to the library, since our software already has all the informations to extract the slices. We agreed with Sanders that we should put interface specifications on a joint document, so as to avoid confusion during the development. We proposed Sanders assistance in that specific development by spending some time with them while testing the interfaces. A "white paper" presenting different options should be composed by Sanders and sent to us.

6) Tests: One piece Brackets

While going over the new software version at Sanders, we have been able to manufacture a sample of two different one piece brackets that were designed by us. These parts are the most complex parts that we have asked Sanders to make. Most particularly, their pads includes a collection of little "pegs" of 0.015 x 0.015 inches. These are very little details that are correctly reproduced by the machine.

Surface finish can be improved by laying down less material.

Conclusion:

The Sanders **Model Maker** is a very ingenious machine that performs correctly when the design is appropriate and should be able to maintain our tolerances (± 0.001 inch). The Wax parts produced are fragile but are not intended to be used as such: they will be used as masters for casting. Operation wise, **Model Maker** is easy to handle and its software is in continuous progress. It is essential with this machine that our future operator is well trained and maintain the machine correctly. The current version of the machine seems to be very sensitive to its environment (heat, vibration ...) while the next version could be faster and more reliable if we believe Sanders claims.

Sanders is a small company but is easy to contact and its people are very customer oriented. A good support is to be expected from this company, since this machine and its technology is relatively new on the market.

As far as cost of operation, this machine has a very good benefit since the material used (wax) is cheap, and the machine can work unattended so the operator cost is low. The material is provided only through Sanders while it actually does not manufacture the wax.

Eric CHAPOULAUD